

CERTIFICATE OF ANALYSIS

(Certificate No. KMA010008-01)

Release Date: 20/08/2024

Re-test Date: 19/08/2027

Amitriptyline Hydrochloride Related Compound B

Identification

Chemical Name :

5-[3-(Dimethylamino)propyl]-10,11-dihydro-5H-dibenzo[a,d][7]annulen-5-ol (as per EP) ; 5-[3-(dimethylamino)propyl]-10,11-dihydro-5H-dibenzo[a,d]-cyclohepten-5-ol (as per USP)

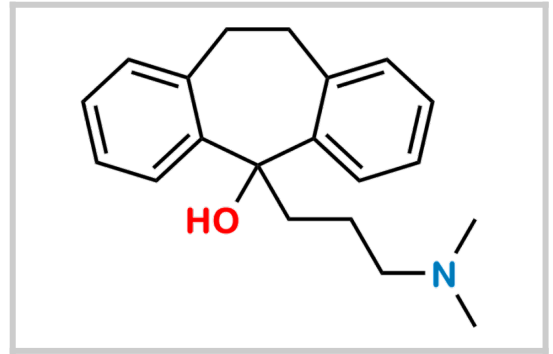
Alt. Name : Amitriptynol (USP) ; Amitriptyline
USP Related Compound B

CAT No. : KMA010008

CAS No. : 1159-03-1

Molecular Formula : C₂₀H₂₅NO

Molecular Weight : 295.4



Analytical Information

Batch No. : KMPS/AMI/B/010

Description : Off White Solid

HPLC Purity : 97.98 %

Weight Loss By TGA : 3.01 %

% Potency : 95.03 %

Solubility : Acetonitrile

Mass : Confirm

IR : Confirm

¹H NMR : Confirm

Additional Information

Long Term Storage : Store at 2-8 deg. C for long term storage

Shipping Condition : Product is stable to be Shipped at Room Temperature

% Potency = [100 - 3.01(Weight Loss By TGA)] x [97.98(HPLC Purity)]/100 = 95.03 %

-Re-tested on 20.08.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		31/12/2024
Reviewed & Approved By	Quality Control	Jatin Patel		31/12/2024

Attachments : COA, HPLC, MASS, ¹HNMR, IR and TGA